K011038

510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as Amended.

Company Name:	Sulzer Dental Inc.
Address:	1900 Aston Avenue, Carlsbad, CA 92008-7308
Telephone Number:	760-431-9515
Registration Number:	2023141
Contact Person:	Diana Smith
Date Summary Prepared:	March 30, 2001
Classification Name:	Implant, Endosseous (76DZE)
Common/Usual Name:	Dental Implant System
Device Trade Name:	Taper-Lock Dental Implant System

The primary device used for comparison in this summary is the dental implants and prosthetic components cleared under K953101.

1. **Intended Use:**

   Sulzer Dental's implant systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, or as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.1mm and 4.7mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

2. **Description:**

   Taper-Lock implants are available with a selective HA surface or a selective roughened surface. They are available in 3.3mm, 4.1mm, and 4.7mm diameters and lengths of 8, 10, 13, and 16mm. All implants have an external hex connection and are fabricated from commercially pure grade 4 titanium. The implants are all provided sterile.

3. **Technological Characteristics:**

   There has been a modification to the Taper-lock implant with the addition of a 3.3mm and 4.7mm diameter. The implant/abutment interface remains unchanged. There has been no change to the implant materials or to the implant/abutment interface.

4. Comparison Analysis:

The overall design of the Taper-Lock implants are similar to the predicate implants. See **Table 1** below for a comparison of the Taper-Lock implants and the predicate devices.

Table 1: Summary of Comparison

Design Feature	Predicate	Taper-Lock
Implants		
Implant Body	Screw type	Same
Selective HA surface	HA coating except for region of apical threads	Same
Selective Roughened surface	Not Available	roughened surface except for region of apical threads
Implant / Abutment Interface	Tapered External Hexagon	Same
Platform Diameter	4.1mm	Same
Implant Diameter(s)	4.1mm	3.3mm, 4.1mm & 4.7mm
Implant Lengths	8, 10, 13, 15 & 18mm	8, 10, 13 & 16mm
Implant Material	Commercially Pure Titanium	Commercially Pure Titanium
Prosthetic Components	Hex Lock Abutments, Angled Abutments, Ball Attachments, Tapered Abutment System, Spectra-Cone System, Copings	Same
Manufacturing		
Packaging	Double vial system	Double vial system
Sterilization	Gamma irradiation	Gamma irradiation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2001

Ms. Diana Smith
Regulatory Affairs Associate
Sulzer Dental, Incorporated
1900 Aston Avenue
Carlson, California 92008-7308

Re: K011038
Trade/Device Name: Taper-Lock Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 4, 2001
Received: April 5, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K011038

Device Name: Taper-Lock Dental Implant System

Indications for Use:

Sulzer Dental Implant Systems are designed for use in edentulous mandibles or maxillae for attachment of complete denture prostheses, as a terminal or intermediary abutment for fixed or removable bridgework, or as a freestanding single tooth replacement. The use of the 4.1mm or 4.7mm implant is recommended when the quantity and density of bone would dictate the use of an implant larger than 4.0mm.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011038